REMARKS

This Amendment is responsive to the Office Action dated June 27, 2007. Applicant has amended claims 3, 22, 69 and 71. Claims 1-15, 17-27 and 69-71 are pending. Claims 7, 10 and 13 were previously withdrawn due to restriction. The Office Action indicated that claims 24 and 71 were also withdrawn as reading on a species that was not elected in response to the Election Requirement dated May, 31, 2006.

Interview Summary

Applicant would like to thank the Examiner for discussing the application with Applicant's representative (undersigned) during a telephonic interview on September 25, 2007. The Examiner indicated that the rejection of claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15 and 17-27 under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111041 A1), which is item 14 in the Office Action, was inadvertently included in the Office Action, and that Applicant did not need to respond to this ground for rejection. The remaining objections and rejections were not discussed. No agreements were reached, and no exhibits were presented.

Claim Objections

The Office Action objected to claim 3 because the positive recitation of "comprising" in line 2 appeared to be a typographical and/or grammatical error. Applicant has amended claim 3 to correct this error.

The Office Action also objected to claim 69 because the positive recitation of "each of the plurality of therapy parameter sets" in lines 14 and 17 appeared to lack antecedent basis. Applicant has amended claim 69, and submits that the amended claim overcomes this objection.

Withdrawal of these objections is respectfully requested.

Claim Rejection Under 35 U.S.C. § 112

The Office Action rejected claim 69 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action stated that claim 69 is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.

Applicant has amended claim 69 for purposes of clarification. Furthermore, with respect to the relationship between the "values of at least one sleep quality metric" and the "at least one activity metric," Applicant submits that claim 69 clearly states that the at least one activity metric is based on the activity levels associated with the therapy parameter set. Claim 69 further states that each of the activity levels determined when the patient is not attempting to sleep is associated with the one or more of a plurality of therapy parameter sets that was used to deliver therapy when the activity level was determined. Therefore, it is clear that the at least one activity metric is distinct and differs from the values of at least one sleep quality metric.

Applicant submits that claim 69, as amended, particularly points out and distinctly claims the subject matter, as required by 35 U.S.C. 112, second paragraph.

Claim Rejection Under 35 U.S.C. § 102

The Office Action rejected claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, 17-23, 25-27, 69 and 70 under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111040 A1, herein referred to as Ni '040). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Ni '040 fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e).

Claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, 17-23 and 25-27

For example, the Ni fails to teach or suggest a method comprising monitoring a plurality of physiological parameters of a patient via a medical device, wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity, determining when the patient is attempting to sleep, determining values of at least one sleep quality metric that is indicative of sleep quality based on values of at least one of the physiological parameters when the patient is attempting to sleep, periodically determining an activity level of the patient based on at least one of the physiological parameters, and determining a value of at least one activity metric based on activity levels determined when the patient is not attempting to sleep, as recited by Applicant's claim 1.

Ni '040 fails to disclose or suggest determining when a patient is attempting to sleep, as recited by independent claim 1. Instead, Ni '040 describes detecting when a patient is sleeping

by detecting sleep onset and termination. The system described in Ni '040 compares a sleep-related signal to a threshold value and detects sleep based on the comparison. Ni '040 does not disclose or suggest determining when a patient is attempting to sleep. As one example, Ni '040 does not disclose or suggest detecting when a patient is awake but attempting to sleep. Ni '040 is limited to determining whether a patient is sleeping.

Ni '040 also fails to disclose or suggest determining when the patient is attempting to sleep by comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold, as recited by claim 6. Although paragraphs [0048], [0057], [0084], [0085], and [0095] of Ni '040 describe comparing a signal to a sleep threshold, Ni '040 fails to disclose or suggest comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold.

As another example, with respect to claim 11, Ni '040 fails to disclose or suggest that the sleep quality metric comprises sleep latency, and determining values of the sleep quality metric comprises identifying a first time when the patient is attempting to fall asleep, identifying a second time when the patient falls asleep based on at least one of the physiological parameters, and determining an amount of time between the first and second times. Ni '040 do not disclose or suggest identifying a first time when the patient is attempting to fall asleep. Ni '040 merely describes identifying when the patient actually falls asleep. For at least these reasons, Ni '040 clearly fails to disclose or suggest determining an amount of time between a first time when the patient is attempting to fall asleep and a second time when the patient falls asleep.

Further, with respect to claim 19, Ni '040 does not disclose or suggest determining a percentage of time that activity levels were above a threshold, or determining a percentage of time that activity levels were below a threshold. Paragraphs [0046] and [0099] of Ni '040 discuss disordered breathing detection methods, but do not suggest determining a percentage of time above or below a threshold.

Ni '040 also fails to disclose or suggest a medical device comprising at least one of a trial neurostimulator and a trial pump, as recited by claim 27. Ni '040 makes no mention of a trial neurostimulator or a trial pump. Instead, Ni '040 describes implementing sleep detection

methods within a cardiac rhythm management system or a chronic hypoglossal nerve stimulator.[1] Ni '040 does not disclose or suggest a trial neurostimulator or a trial pump.

Claims 69 and 70

Furthermore, Ni '040 fails to teach or suggest a method comprising monitoring a plurality of physiological parameters of a patient via a medical device, wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity and wherein the medical device delivers a therapy to the patient according to a plurality of therapy parameter sets, determining when the patient is attempting to sleep, determining values of at least one sleep quality metric that is indicative of sleep quality based on values of at least one of the physiological parameters when the patient is attempting to sleep, periodically determining an activity level of the patient based on at least one of the physiological parameters, associating each of the at least one determined sleep quality metric values and each of the activity levels determined when the patient is not attempting to sleep with a current therapy parameter set, for each of the plurality of therapy parameter sets, determining a representative value for each of the at least one sleep quality metric based on the sleep quality metric values associated with the sleep quality metric and the therapy parameter set, and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set, as recited by Applicant's amended independent claim 69.

As described with respect to claim 1, Ni '040 does not disclose or suggest determining when a patient is attempting to sleep. For example, Ni '040 does not disclose or suggest detecting when a patient is awake but attempting to sleep. Ni '040 is limited to determining whether a patient is actually sleeping.

Further with respect to claim 69, Ni '040 fails to disclose or suggest associating sleep quality metric values and activity levels with the one or more of a plurality of therapy parameter sets that was used to deliver therapy at the time the values or levels were determined, determining a representative value for a sleep quality metric based on values associated with a therapy parameter set, or determining an activity metric value based on activity levels associated

[1] Ni '040, paragraph [0050].

with a therapy parameter set. Applicant's claim 69 describes at least one sleep quality metric that is indicative of sleep quality and further describes determining a representative value for each of the at least one sleep quality metric for each therapy parameter set. More specifically, claim 69 requires associating determined values of the at least one sleep quality metric with the one or more parameter sets that were in use when the values were determined, and determining a representative value for each of the at least one sleep quality metric for each therapy parameter set based on the values associated with the therapy parameter set. Similarly, claim 69 requires associating activity levels determined when the patient is not attempting to sleep with the one or more therapy parameter sets that were used when the activity levels were determined, and determining at least one activity metric value for each therapy parameter set based on the activity levels associated with the therapy parameter set. In this manner, embodiments according to claim 69 may facilitate evaluation of each of a plurality of therapy parameter sets based on the patient's activity and sleep quality during delivery of therapy according to that therapy parameter set.

Ni '040 does not disclose or suggest associating sleep quality metric values or activity levels with the one or more therapy parameter sets in use when the levels or values were determined. Applicant's specification, for example at paragraph [0019], states that when the medical device determines a sleep quality metric value or an activity level, the medical device may identify the current therapy parameter set when the value or level is determined, and may associate that value or level with the therapy parameter set. Associating activity and sleep quality information with different therapy parameter sets may permit a user to evaluate relative efficacy of the therapy parameter sets.[2]

Ni '040 describes a method of detecting disordered breathing that may be implemented within a microprocessor of a cardiac rhythm management (CRM) system. In this manner, the CRM system may provide cardiac pacing therapy and detect occurrences of disordered breathing. Ni '040 does not disclose or suggest associating sleep quality metric values or activity levels with a therapy parameter set.

Ni '040 also fails to disclose or suggest determining a representative value for each of the at least one sleep quality metric and at least one activity metric for each of the therapy parameter

[2] *See* Summary of Invention of present application.

sets based on sleep quality metric values and activity levels associated with the therapy parameter set. Since Ni '040 fails to disclose or suggest associating sleep quality metrics or activity levels with a therapy parameter set, Ni '040 also fails to disclose or suggest determining a representative value for a sleep quality metric or an activity metric based on the values and levels associated with the therapy parameter set. The Office Action did not discuss this requirement of claim 69. Applicant respectfully requests that this requirement is addressed in any subsequent Office Action.

In order to support an anticipation rejection under 35 U.S.C. § 102(e), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[3] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(e) is improper.[4]

The applied references fail to disclose each and every limitation set forth in independent claims 1 and 69. Claims 2, 3, 5, 6, 8, 9, 11, 12, 14, 15, and 17-27 are dependent upon claim 1 and claim 70 is dependent upon claim 69. These dependent claims are also in condition for allowance. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, 17-27, 69 and 70 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

The Office Action rejected claims 4 under 35 U.S.C. 103(a) as being unpatentable over Ni '040 in view of Sheldon (US 5,593,431) or, alternatively over Ni '041 in view of Sheldon. Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claim 4 is dependent upon claim 3, which directly depends from independent claim 1. Ni '040 and '041 fail to disclose or suggest the requirements of claim 1 for at least the reasons stated

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[3] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").

[4] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

previously in this Amendment. Sheldon lacks any teaching sufficient to overcome the basic deficiencies described above with respect to the Ni references. Therefore, claim 4 is also in condition for allowance. Withdrawal of this rejection is requested

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 10-26-07

By: _____

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